K092227

INTEGRA
LIFESCIENCES CORPORATION
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510(k) Summary

FEB 17 2010

Submitted by: Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact Person: Jennifer J. Bosley, Regulatory Affairs Manager
Integra Medical Instrument Group
589 Davies Drive
York, PA 17402 USA
Phone: (717) 781-6392 Fax: (717) 840-3509

Date Prepared: July 21, 2009

Device Trade Name: Integra™ Kerrison Rongeurs
Common/Usual Name: Kerrison Rongeur
Proposed Classification: Manual Rongeur
21 CFR 882.4840 Class II, 84 HAE, Neurology

Device Description:
Integra™ Kerrison Rongeurs are reusable stainless steel instruments that are sterilizable and packaged non-sterile. Devices are available with the following features: with or without proprietary surface treatments; 1-6 mm bite sizes; 9 - 15.5 mm jaw openings; 40° and 90° up/down cutting angles; regular and thin/low profile footplates; standard and ejector tips; 4.75 – 15" shaft lengths; and various handle and shaft styles, including Detach®. Integra™ Kerrison Rongeurs are distributed under the following brand names: *Jarit®, Ruggles™, R&B Redmond™(Redmond™), Miltex®, MeisterHand®.*

Intended Use:
Integra™ (*Jarit®, Ruggles™, R&B Redmond™(Redmond™), Miltex®, MeisterHand®*) Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

Predicate Devices:

510(k) #	Device	Manufacturer
Pre-amendment	Jarit Laminectomy Rongeurs	J. Jamner Surgical Instruments (Integra LifeSciences)
Pre-amendment	Ruggles Laminectomy Rongeurs	Ruggles Corp. (Integra LifeSciences)
K902819	Ruggles Laminectomy Rongeurs	Ruggles Corp. (Integra LifeSciences)
K933978	Redmond Ejector Kerrison Rongeur	Redmond Neurotechnologies (Integra LifeSciences)
Pre-amendment	Miltex Kerrison Rongeurs	Miltex, Inc. (Integra LifeSciences)

Substantial Equivalence:
Modified Integra™ Kerrison Rongeurs conform to design specifications and are substantially equivalent to the above legally marketed pre-amendments and predicate devices with respect to intended use, fundamental technology, design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
c/o Jennifer Bosley, MBA, RAC
Regulatory Affairs Manager
Integra Instrument Group
311 Enterprise Drive
Plainsboro, NJ 08536

FEB 17 2010

Re: K092227
Trade/Device Name: Integra Kerrison Rongeurs
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: January 8, 2010
Received: January 11, 2010

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092227

Indications For Use

510(k) Number (if known): K092227

Device Name: Integra™ Kerrison Rongeurs

Indications for Use:

Integra™ (*Jarit®, Ruggles™, R&B Redmond™(Redmond™), Miltex®, MeisterHand®*) Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

Prescription Use ✓ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092227